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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,981	11/19/2003	Binie V. Lipps	FWLPAT013US	8806

7590 11/15/2006

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EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,981	LIPPS ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/06; 1/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christina Borgeest, Ph.D., Art Unit 1649.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-4 and 13, in the reply filed on 28 August 2006 is acknowledged. The traversal is on the ground(s) that the products recited in the claims are related and that the processes of Groups II-VI all use the same peptides. This is not found persuasive for the following reasons. For the sake of clarity, the restriction requirement made by the previous examiner is summarized below:

I. Claims 1-4 and drawn to a peptide composition of matter
II. Claims 5-6 drawn to a method of administration
III. Claim 7 in part drawn to a method of forming antibodies
IV. Claims 8-9, 12 drawn to a method of administering NGF
V. Claim 10 drawn to a method of administering two peptides, a first peptide of five amino acids from N-terminal SEQ ID NO:2 and a second peptide no more than 25 amino acids in total.
VI. Claims 7 in part and 11 drawn to a process of contacting in vitro NGF with an antibody

It is not disputed that SEQ ID NOs: 2, 3 and 4 are closely related and should therefore be examined together in Group I, along with claim 13. However, Groups II-VI are drawn to different methods that are not obvious variants. For instance, prior art disclosing administration of an NGF would not anticipate or render obvious a method of forming

antibodies. Because this would result in at least seven separate and non co-extensive searches, this is a search burden.

The requirement is still deemed proper and is therefore made FINAL.

Claim 13 is new and drawn the compositions of Group I. Claims 1-13 are pending. Claims 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 August 2006. Claims 1-4 and 13 are pending and under consideration.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite a composition, but only recite the peptide portion of the composition. A composition must recite at least two elements, thus the claim is indefinite.

In addition, claims 1-4 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claims are so open ended that they do not recite what the invention actually is. For instance, claim 1 recites "[a] composition of matter comprising a peptide consisting of at least the first five amino

acids from the N-terminal of SEQ ID NO: 2 and no more than 25 amino acids total," thus although the peptide must be no more than 25 amino acids total, there is no limit to how large or small the "composition of matter", which encompasses the peptide, must be. In addition, the "composition of matter" encompasses non-peptidic molecules such as polynucleotides, small inorganic molecules, large organic molecules or antibodies to name a few. The claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant (see MPEP 2171). The claims as written do not clearly define what the composition of matter actually is.

Finally, claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. First, the claim recites a "composition of matter as in claim 1 wherein the peptide produces an antibody...", however, it is not clear how the peptide "produces an antibody." Second, which human body fluids and human origin eukaryotic cells" are intended targets of the peptide? Third, claim 4 also recites "produced in immunological response to an NGF derived from venom", but it is not clear how it is produced and by whom or what venom the NGF is derived from. The claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant (see MPEP 2171), however, the limitations of claim 4 do not point out and distinctly claim what Applicants actually regard as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Oldenberg et al., US 5,814,603, Sept. 29, 1998. Oldenburg et al., teach a PTH analog comprising the sequence of SEQ ID NO: 51 having 35 amino acid residues that contains 5 residues from the N-terminal of SEQ ID NO: 2 "NLGEH" as recited. The reference is silent as to the peptides activity with respect to producing an antibody which has a binding affinity to nerve growth factors from human body fluids and human origin eukaryotic cells that is higher than a binding affinity exhibited by an antibody produced in immunological response to a nerve growth factor derived from venom as recited in claim 4. However, the peptide meets all structural limitations as recited and thus the peptide is deemed to be the same and to provide all requisite functional activities absent convincing factual evidence to the contrary. Note that all the claims recite open language: "a composition of matter comprising..." and because a composition of matter can be a protein comprising a peptide, the limitation of no more

than 25 amino acids total applies only to the comprised peptide and not to the entire composition of matter.

Claims 1-4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (FEBS Lett. 1991; 279: 38-40). Inoue et al., teach a NGF from the venom of the cobra having 116 amino acid residues that contains 5 residues from the N-terminal of SEQ ID NO: 2 "NLGEH" as recited in the claims (see p. 39, Figure 1). The reference is silent as to the polypeptide's activity with respect to producing an antibody which has a binding affinity to nerve growth factors from human body fluids and human origin eukaryotic cells that is higher than a binding affinity exhibited by an antibody produced in immunological response to a nerve growth factor derived from venom as recited in claim 4. However, the polypeptide meets all structural limitations as recited and thus the polypeptide is deemed to be the same and to provide all requisite functional activities absent convincing factual evidence to the contrary. Note that all the claims recite open language: "a composition of matter comprising..." and because a composition of matter can be a protein comprising the peptide NLGEH, the limitation of no more than 25 amino acids total applies only to the comprised peptide and not to the entire composition of matter.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

LORRAINE SPECTOR
PRIMARY EXAMINER